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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER				
GERIDO, DWAN A				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/576,345

Applicant(s)

MARCHANT ET AL.

Examiner

Dwan A. Gerido, Ph.D.

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 April 2006 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/5508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

10576345DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. For claim 3, applicant recites a working zone that is not clearly defined in independent claim 1 from which claim 3 depends. Therefore, it is unclear what structural features define the claimed working zone.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 4, 10, 11, 12, 15, 17, 19, 20, 28, 29, and 32 rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (US 6,210,894).
6. For claim 1, Brennan teaches a substrate comprising an active surface that is non-wetting with respect to a sample liquid (column 4 lines 38-43), a capture zone and an operating zone (column 5 lines 5-23, column 7 lines 14-26), and a means for supplying the sample liquid (column 5 lines 56-61).

7. For claim 4, Brennan teaches the device wherein the capture zone (individual wells) exhibits chemical capture of the sample liquid (column 7 lines 45-53).
8. For claim 10, Brennan teaches a surface rendered wetting by grafting a chemical substance onto the surface (column 5 lines 19-23).
9. For claim 11, Brennan teaches glass as the surface (column 5 lines 19-23),
10. For claim 12, Brennan teaches the grafting material as silane placed on the surface by silanization (column 5 lines 19-23).
11. For claim 15, Brennan teaches a hydrophilic capture zone, and a hydrophobic non-wetting zone (column 5 lines 8-23, claim 3 b, d).
12. For claim 17, Brennan teaches the operating zone having a chemical interaction with the sample (column 9 lines 16-23).
13. For claim 19, Brennan teaches at least one operating zone for detection of a biological species present in the liquid sample (column 7 lines 60-62, column 9 lines 16-18).
14. For claim 20, Brennan teaches the device wherein at least one operating zone is functionalized with a probe to interact with a target present in the sample liquid (column 7 lines 21-26, 45-48, 60-62).
15. For claim 28, Brennan teaches the operating zone being non-wetting with respect to the sample liquid (column 4 lines 37-43)
16. For claim 29, Brennan teaches the active surface consisting of glass (column 5 lines 8-19).
17. For claim 32, Brennan teaches a dispenser as the means for depositing the liquid sample (column 5 lines 56-67, column 7 lines 1-8).

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

21. Claims 2, 3, 5, and 16 rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan (US 6,210,894) in view of Garyantes (US 6,565,813).

22. With regards to claim 2, Brennan teaches a substrate comprising an active surface that is non-wetting with respect to a sample liquid (column 4 lines 38-43), a capture zone and an

operating zone (column 5 lines 5-23), and a means for supplying the sample liquid (column 5 lines 56-61). Brennan does not teach the capture zone having a particular shape.

23. Garyantes teaches a device comprising a plurality of wells having an annular circular shape (Abstract, column 8 lines 63-66, figure 6A). It would have been obvious to one of ordinary skill in the art to modify Brennan in view of Garyantes in order to provide an annular well that conforms to the shape of a liquid droplet. In addition, it would have been obvious to modify Brennan in view of Garyantes as changes in shape within a device require only routine skill in the art (see MPEP 2144.04 IV B).

24. With regards to claim 3, Brennan does not teach a capture zone surrounding multiple working zones. Garyantes teaches that it is advantageous to surround several hydrophilic zones with a hydrophobic zone in order to test multiple samples without contaminating each individual sample liquid. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Brennan by surrounding several hydrophilic zones with a hydrophobic zone in order to test multiple samples without contaminating each individual sample liquid.

25. With regards to claim 5, Brennan does not teach a capture zone being in, a projection on the surface. Garyantes teaches that it is advantageous to form the capture zone as a protrusion in order to allow formation of a virtual well for a hydrophilic layer (column 9 lines 37-45, 55, 56). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Brennan with the protrusions of Garyantes in order to allow formation of a virtual well.

26. With regards to claim 16, Brennan does not teach a capture zone and an operating zone in a hollow or as a projection relative to the surface. Garyantes teaches that it is advantageous to form the capture zone or the operating zone as a hollow or a projection relative to the surface in order to allow formation of virtual wells for a hydrophilic layer (column 9 lines 37-51). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Brennan with the protrusions of Garyantes in order to allow formation of a virtual well..

27. Claims 6, 8, 9, 13, 14, 18, 21, 22, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan (US 6,210,894) in view of Heller (US 6,017,696).

28. With regards to claim 6, Brennan teaches a substrate comprising an active surface that is non-wetting with respect to a sample liquid (column 4 lines 38-43), a capture zone and an operating zone (column 5 lines 5-23), and a means for supplying the sample liquid (column 5 lines 56-61). Brennan does not teach a device wherein at least one capture zone is an electrode.

29. Heller teaches that it is advantageous to place electrodes in microlocation zones (capture zone) in order to control electrophoretic transport of molecules in a sample liquid (column 11 lines 6-10, 54-61). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Brennan placing electrodes in microlocation zones (capture zone) in order to control electrophoretic transport of molecules in a sample liquid (column 11 lines 6-10, 54-61). .

30. With regards to claim 8, applicant does not provide any structural limitations regarding the claimed electrode; therefore, the electrode taught by Brennan in view of Heller would be fully capable of capture by electrowetting as recited in the instant claim. In addition, the instant

claim is sufficiently broad so as to not overcome limitations taught by the prior art; therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Brennan in view of Heller in a manner wherein the electrode is configured for capture by electrowetting.

31. With regards to claim 9, Brennan does not teach an electrode consisting of a noble metal. Heller teaches that it is advantageous to construct electrodes from noble metals in order to complement other materials in the assay device (column 15 lines 36-40). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Brennan with a noble metal electrode in order to complement other materials in the assay device.

32. With regards to claim 13, Brennan does not teach an electrode made of gold. Heller teaches that it is advantageous to form electrodes from gold in order to complement other materials within the assay device (column 15 lines 36-40). The limitations of rendering the electrode wetting by physisorption of a thiol is regarded as intended use as there are various known methods of rendering an electrode wetting. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Brennan to include a gold electrode in order to complement other materials in the assay device.

33. With regards to claim 14, Brennan does not teach the wetting chemical as an alcohol. Heller teaches that it is advantageous to utilize hydroxyl groups as the wetting agent for an aqueous solution (column 17 lines 4 and 5). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Brennan by employing an alcohol for the wetting chemical as hydroxyl groups are useful with aqueous solutions.

34. With regards to claim 18, Brennan does not teach the operating zone as an electrochemical microcell. Heller teaches that it is advantageous to construct an electrochemical microcell in order to extract specific molecules from a sample (column 12 lines 35-54). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Brennan by constructing an electrochemical microcell in order to extract specific molecules from a sample.

35. With regards to claim 21, Brennan does not teach an electrode of an electrochemical microcell. Heller teaches an electrochemical microcell (column 12 lines 35-54) wherein the electrode exhibits wetting properties (column 16 lines 18-22). The claim language stating that the electrode is used for operation of an electrochemical microcell is regarded as intended use and is not given patentable weight. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Brennan in view of Heller to gain the advantage of providing an electrochemical microcell comprising an electrode with wetting properties in order to extract compounds from a variety of aqueous solutions.

36. With regards to claim 22, Brennan does not teach an electrode with a probe to interact with a target in a sample liquid. Heller teaches that it is advantageous to attach a probe to the electrode in order to extract specific target molecules from a sample (column 16 lines 7-13, column 17 lines 4-13, 26 and 27). It would have been obvious to modify the device Brennan in order to provide a probe attached to the electrode in order to extract specific target molecules from a sample.

37. With regards to claim 25, Brennan does not teach an electrode wherein a biological probe is attached for binding targets in a sample liquid. Heller teaches that it is advantageous to utilize

DNA, enzyme, and antibody probes in order to allow for efficient binding and detection of the target of interest (column 20 lines 13-25). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Brennan in view of Heller in order to improve specificity of a reaction by utilizing a probe that specifically binds a target molecule within the sample liquid.

38. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan (US 6,210,894) in view of Heller (US 6,017,696) as applied to claim 22 above, and further in view of Marx et al., (US 5,440,025).

39. With regards to claim 23, Brennan in view of Heller teach a device wherein an electrode is labeled with a probe aimed at binding a target within a sample liquid. Brennan in view of Heller does not teach the probe attached to an electrically conductive polymer. Marx et al., teach that it is advantageous to extract a nucleic acid with an electrically conductive polymer to gain the advantage of binding a nucleic acid without denaturation. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Brennan in view of Heller in further view of Marx et al., in order to prevent denaturation of the nucleic acid as taught by Marx et al. advantages.

40. With regards to claim 24, Marx et al., teach polypyrrole as the electrically conductive polymer. It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize polypyrrole as the conductive polymer within the device of Brennan to gain the advantage of preventing denaturation of the nucleic acid as taught by Marx et al.

41. Claims 30-35, 38, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan (US 6,210,894).

42. With regards to claim 30, Brennan teaches an operating device comprising an active surface that is non-wetting with respect to a sample liquid (column 4 lines 38-43), a capture zone and an operating zone (column 5 lines 5-23), and a means for supplying the sample liquid (column 5 lines 56-61). Brennan does not teach an operating plate comprising several operating devices. The mere duplication of parts has no patentable significance unless a new and unexpected result is produced. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the operating device of Brennan to include multiple operating devices in order to process multiple samples simultaneously (see MPEP 2144.04 VI B).

43. With regards to claim 31, Brennan teaches the operating devices as an array (column 8 line 2, column 9 lines 16-18).

44. With regards to claim 32, Brennan teaches a dispenser wherein the dispenser delivers a drop of liquid per capture zone (column 8 lines 37-44).

45. With regards to claims 33 and 38 Brennan teaches an operating box (figure 7) comprising, a container with means for introduction and withdrawal of a liquid (column 5 lines 56-67, figures 5 #'s 2 and 3), and an operating device (column 4 lines 38-43, figure 7 #6). The means for withdrawal of the liquid as taught by Brennan meets the limitations of the instant claim in that applicant does not indicate a specific mechanism for liquid withdrawal. Paragraph 0129 of the instant specification states that "withdrawal of the liquid can be carried out by any appropriate means known to those skilled in the art" therefore the withdrawal means taught by Brennan would be fully capable of performing as that of the instant claim.

46. With regards to claim 34, Brennan teaches a method of washing the array plate by flooding the surface with a liquid (column 8 lines 53-57. It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the washing step as taught by Brennan to withdraw the sample liquid from the array surface in order to remove deposited samples prior to application of a different sample.

47. With regards to claim 35, Brennan teaches an operating box purged with argon gas to maintain anhydrous conditions (column 8 lines 58-60). It would have been obvious to one of ordinary skill in the art to modify the teachings of Brennan wherein the vapor of the sample is injected into the operating box in order to maintain optimal conditions for application of a sample liquid.

48. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan (US 6,210,894) as applied to claim 33 above, and further in view of Grant et al., (US 5,624,815).

49. With regards to claim 36, Brennan does not teach a suction pump for withdrawal of a sample liquid. Grant et al., teach that it is advantageous to utilize a suction pump for liquid withdrawal in order to efficiently remove excess liquid (column 6 lines 63 and 64). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Brennan with the pump of Grant et al., in order to efficiently remove excess liquid.

50. Claims 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan (US 6,210,894) in view of Rava et al., (US 5,545,531).

51. With regards to claim 39, Brennan teaches With regards to claim 30, Brennan teaches an operating device comprising an active surface that is non-wetting with respect to a sample liquid

(column 4 lines 38-43), a capture zone and an operating zone (column 5 lines 5-23), and a means for supplying the sample liquid (column 5 lines 56-61). Brennan does not teach the device as a biological chip.

52. Rava et al., teach that it is advantageous to form a multiple biological chips wherein probes are exposed on the surface of a substrate in order to bind an analyte in a liquid sample (Abstract, column 4 lines 48-52). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Brennan in view of Rava et al., in order to provide increased throughput, thereby allowing multiple biological samples to be analyzed on a single device.

53. With regards to claim 40, Brennan teaches a substrate for binding nucleic acids (Example 4).

54. With regards to claim 41, Brennan teaches the device as an operating box (column 8 lines 50-57, figure 7).

55. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan (US 6,210,894).

56. With regards to claim 42, Brennan teaches a method of fabricating a device comprising a substrate with a surface configured to become the active surface (column 2 lines 32-35, column 4 lines 36-43), structuring the surface to form an operating zone that is covered by a liquid droplet (column 2 lines 41-43, column 7 lines 14-16, figures 2a, 3), treating the surface so as to render it non-wetting with respect to the sample liquid (column 4 lines 37-43), structuring the surface to form a capture zone for a sample (column 2 lines 36-38, column 7 lines 21-26, figure 2a)

wherein the capture zone is arranged in a manner that surrounds the operating zone (figures 2a, 3).

Response to Arguments

57. Applicant's arguments filed December 15, 2008 have been fully considered but they are not persuasive. The objection to claim 30 and rejection of claim 23 under 35 U.S.C. 112 have been removed. Applicant argues that reference to Brennan fails to teach or suggest the claimed "at least one operating zone separate from the capture zone. The examiner respectfully disagrees with applicants arguments. Brennan teaches treating a glass surface with a coating, ablating specific regions of said coating, and subsequently treating the exposed regions with a separate coating all of which reads on the claimed capture and operating zones (column 5 lines 5-23, column 7 lines 14-26, figure 3). The secondary references applied in the above office action are utilized in combination with Brennan as described above; therefore, the rejections of Brennan in view of Garyantes, Heller, Marx, Grant, and Rava are upheld by the examiner.

Conclusion

58. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwan A. Gerido, Ph.D. whose telephone number is (571)270-3714. The examiner can normally be reached on Monday - Friday, 9:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lyle A Alexander/
Primary Examiner, Art Unit 1797

DAG